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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,616	02/27/2002	Chihiro Uematsu	NITT.0065	1757
7590	11/28/2003		EXAMINER	
Stanley P. Fisher Reed Smith LLP Suite 1400 3110 Fairview Park Drive Falls Church, VA 22042-4503			HORLICK, KENNETH R	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/083,616

Applicant(s)

UEMATSU ET AL.

Examiner

Kenneth R Horlick

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8, 10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 8 and 11 is/are rejected.
- 7) ☒ Claim(s) 7 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended claim 6 and new claim 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (US 6,110,710).

Claim 6 is drawn to a method comprising: carrying out PCR using four types of primers which have non-complementary sequences at the 5'-ends and complementary sequences at the 3'- ends, wherein the base at the 5'-end is different in the four types of primers; analyzing the results of the PCR and requiring adenylation efficiencies based on the analysis; and determining which one of the four types of primers is most likely to undergo adenylation. Claim 11 is drawn to a similar method, with the added step of synthesizing the appropriate determined primer.

Smith et al. disclose such a method in Fig. 1 and columns 7-8. It is noted that the first four primers with added tails in Fig. 1 comprise tails which are identical except for the 5'-terminal base, which is different among them.

2. With respect to the above rejection, the arguments of the response filed 09/15/03 have been fully considered, but are not found persuasive. On page 10 of the response, it is argued that "...Smith fails to teach how to select the candidate sequences most favoring adenylation". It is further argued on page 9 that this reference fails to teach or suggest the steps of: determining one out of four types of primers as a sequence which is most likely to undergo adenylation; and synthesizing primers having the sequence determined as most likely to undergo adenylation.

However, it is submitted that Smith et al. do in fact provide all these teachings as set forth in the prior Office action; indeed, these teachings are at the very heart of the invention disclosed by Smith et al. The data in Fig. 1 showing the first four tailed primers clearly teaches how to select the candidate sequences most favoring adenylation as revealed in the “% + A” column, and synthesis of primers having the selected tail sequences for use in appropriate applications is clearly set forth in columns 7 and 8, as well as in claims 1 and 2. Thus the claimed invention cannot be distinguished from the disclosure of Smith et al.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al.

This claim is drawn to a method similar to claim 6 as described and rejected above, further comprising: storing data regarding the primers as obtained in the method; inputting a sequence of target DNA; determining an amplification area in the target DNA; designing appropriate amplification primers; extracting anchor sequences from the stored data; designing an anchored reverse primer based on the stored data; and calculating probabilities of secondary structure in the primers.

Smith et al. do not disclose these additional steps.

One of ordinary skill in the art would have been motivated to add these further steps to the method of Smith et al. because they would have merely involved straightforward, logical reasoning. The further steps simply involve data input/storage and routine optimization of PCR parameters, both of which were indisputably well known and common knowledge in the art at the time of the invention, and thus cannot contribute to patentability. For example, secondary structure was well recognized to be undesirable in primers as leading to deleterious results in PCR amplification. Indeed, the instant specification recites on page 26, "...base sequences of a PCR forward and a PCR reverse primer...are so designed according to a conventional method as to have an appropriate T_m value and not to form either an interprimer or intraprimer secondary structure" (emphasis added). Thus, this statement can be taken as an admission that this additional step of checking for secondary structure follows straightforward reasoning and does not contribute to patentability. Further, the benefits of data storage, inputting, and extraction, such as might be obtained using a computer, would have surely been self-evident. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed method.

4. Claims 7 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Further to the method of claim 6 wherein four primers are tested to determine the best base at the 5'-end position, claims 7 and 10 require testing four additional primers having a fixed 5'-end position to determine the best base at the next base in from the 5'-end. While Smith et al. investigate the base positions 2, 3, and 4 from the 5'-end of primers to some extent, it can be seen in Smith et al. Fig. 1 that this is not done in the systematic manner of instant claims 7 and 10. For example, in the set of primers in said Fig. 1, only C and T are represented in the second position from the 5'-end.

5. No claims are allowable.

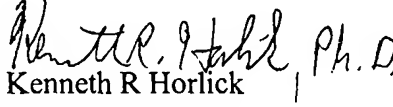
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Kenneth R Horlick
Primary Examiner
Art Unit 1637

11/18/03